application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Risperdal® (risperidone). Risperdal® is indicated for the management of the manifestations of psychotic disorders. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Risperdal® (U.S. Patent No. 4,804,663) from Janssen Pharmaceutica N.V., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 22, 1994, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Risperdal® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Risperdal® is 1,940 days. Of this time, 1,316 days occurred during the testing phase of the regulatory review period, while 624 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* September 8, 1988. Applicant claims September 7, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 8, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* April 15, 1992. FDA has verified the applicant's claim that April 15, 1992, was the date the new drug application (NDA) for Risperdal® (NDA 20–272) was initially submitted.

3. *The date the application was approved:* December 29, 1993. FDA has verified the applicant's claim that NDA 20–272 was approved on December 29, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 683 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 31, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 27, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 16, 1994.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 94–21284 Filed 8–29–94; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94E–0071]

Determination of Regulatory Review Period for Purposes of Patent Extension; Zosyn®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Zosyn® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Zosyn® (tazobactam sodium and piperacillin sodium). Zosyn® is indicated as for the treatment of patients with moderate to severe infections caused by piperacillin resistant, piperacillin/tazobactam susceptible, β-lactamase producing strains of the designated microorganisms in certain specified conditions. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Zosyn® (U.S. Patent No. 4,562,073) from Taiho Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 19, 1994, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Zosyn® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Zosyn® is 1,819 days. Of this time, 1,038 days occurred during the testing phase of the regulatory review period, while 781 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: October 31, 1988. The applicant claims July 10, 1988, as the date the investigational new drug application (IND) for Zosyn® (IND 31,705) became effective. However, IND 31,705 was received on June 14, 1988, and it was placed on clinical hold on July 1, 1988. It was removed from clinical hold on October 31, 1988, making the IND effective date October 31, 1988.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act*: September 3, 1991. The applicant claims August 30, 1991, as the date the new drug application (NDA) for Zosyn® (NDA 50–684) was initially submitted. However, FDA records indicate that NDA 50–684 was submitted on September 3, 1991.

3. *The date the application was approved*: October 22, 1993. FDA has verified the applicant's claim that NDA 50–684 was approved on October 22, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,358 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 31, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 27, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 16, 1994.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 94–21286 Filed 8–29–94; 8:45 am]

BILLING CODE 4160–01–F

Gene Therapy Production Issues; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss gene therapy production issues. The meeting is designed to obtain public testimony from biomedical researchers, academia, biotechnology associations, governmental agencies, and individuals and organizations with relevant information concerning gene vector production issues.

DATES: The public meeting will be held on Monday, September 12, 1994, from 6 p.m. to 7:30 p.m., immediately following the National Institutes of Health, Recombinant DNA Advisory Committee meeting.

ADDRESSES: The public meeting will be held at the National Institutes of Health, Bldg. 31C, 9000 Rockville Pike, conference room 7, Bethesda, MD. No registration is required.

FOR FURTHER INFORMATION CONTACT:

For information regarding the meeting: John G. Bishop, Center for Biologics Evaluation and Research (HFM–515), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–402–1336, FAX 301–496–7027.

For information regarding this notice: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: The field of gene therapy is rapidly evolving. New approaches to genetic modification of somatic cells for the mitigation of human disease are being developed in ever increasing numbers. The investigators who wish to pursue gene therapy approaches are also increasing in number. FDA is interested in exploring with the public and industry means to overcome impediments to the development of useful therapeutics for a variety of human diseases without diminishing patient safety.

As part of this process, FDA's Center for Biologics Evaluation and Research is holding a public meeting to discuss practical concerns relating to gene therapy vector production issues. The objectives of the meeting will be to: (1) Solicit public testimony from biomedical researchers, university faculty members and administrators, biotechnology associations, Federal and